

AMENDMENTS TO THE DRAWINGS

Replacement Sheets Nos. 1-5 are submitted herewith in Appendix A. Replacement sheets Nos. 1-5 contain Figures 1-7.

Applicant has formalized Figures 1-7. Figure 3B has been amended to include reference numeral 300, as described in the Specification at page 11, lines 5-6. Applicant has also amended Figures 5A and 5B to fix a misspelling of the word “threshold.” No new matter has been added.

The replacement sheets replace all previous drawing sheets containing Figures 1-7.

Attachment A: Replacement Sheets Nos. 1-5

REMARKS

Reconsideration of this application in light of the amendments and the following remarks is respectfully requested.

Status of the Claims

Claims 1-36 and 39-40 are pending. Claims 37-38 were previously cancelled.

Claims 1, 10, and 18 have been amended. Support for the amendments can be found in the Specification at page 10, lines 1-5, page 11, lines 1-5, and in Figures 2 and 6B.

Claims 39 and 40 have been added. Support for added claim 39 can be found in the originally-filed claim 3 and in Figure 2. Support for added claim 40 can be found in the Specification at page 10, lines 1-5, page 11, lines 1-5, and in Figures 2 and 6B.

No new matter has been added.

Objection to the Drawings

The Examiner has objected to the Figures for being informal. Applicant has formalized Figures 1-7 and has attached Replacement Drawing Sheets Nos. 1-5 containing Figures 1-7 herewith in Appendix A. Applicant respectfully requests reconsideration of this objection.

Rejection under 35 U.S.C. §112

Claims 10-17 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite. The Examiner contends that the feature of “an electrode that is smaller than 10 μm ” recited in claim

10 is unclear since it implies that the electrode has both the length and width direction being less than 10 μm .

Applicant has amended claim 10 to recite that the “electrode . . . is smaller than . . . μm in diameter.” Applicant has made similar amendments to claims 1 and 18 as well. Applicant respectfully requests reconsideration and withdrawal of this rejection.

Rejection under 35 U.S.C. §102

Claims 1-5, 10, 14, 18-21, and 26-31 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,843,093 to Howard, III (“Howard”).

With respect to the rejection of independent claims 1 and 18, Applicant respectfully traverses the rejection. Independent claims 1 and 18 recite that the electrode is “deployed in a blood vessel proximate to the neural tissue.” In the claimed invention, a n-electrode 220 is deployed within a blood vessel so that the sensing end of the electrode is proximate to the point at which a nerve to be monitored is closest to the blood vessel. *See*, Specification, page 9, lines 9-12.

Applicant submits that Howard neither discloses, nor suggests, deploying the electrode “in a blood vessel proximate to the neural tissue,” as recited in independent claims 1 and 18. In contrast, Howard discloses a microelectrode 135A located within a shaft 137 that is inserted into specific regions of a patient’s brain (e.g., globus pallidus, primary auditory cortex, etc.). *See*, Howard, col. 18, lines 45-50, col. 24, lines 51-54, and Figures 19a-19g, 20. The shaft 137 has a diameter of 1-4 mm, and is inserted into a person’s brain via an introducer tube 101 through a burr hole that is drilled into the person’s skull. *See*, Howard, col. 26, lines 43-44, and Figures 17, 18, 19a, 19b, and 19g.

Applicant submits that drilling a burr hole in the skull in order to insert the shaft 137 is **not** the same as, nor equivalent to, deploying an electrode in a blood vessel proximate to the neural tissue. Further, contrary to the Examiner's position, Applicant submits that the Figures in Howard cited by the Examiner (Howard, Figures 2, 8, 10, and 11A) fail to disclose or suggest deploying an electrode in a blood vessel. *See*, Detailed Action, Item 5, page 4.

Accordingly, Applicant submits that Howard fails to disclose or suggest that the electrode is "deployed in a blood vessel proximate to the neural tissue," as recited in independent claims 1 and 18. Therefore, Applicant submits that Howard fails to disclose each and every feature recited in independent claims 1 and 18. Thus, Howard does not anticipate the invention recited in independent claims 1 and 18.

Claims 2-5 and 26-27 depend from claim 1. Claims 19-21 and 30-31 depend from claim 18. Applicant submits that dependent claims 2-5, 19-21, 26-27, and 30-31 are patentable for at least the same reasons discussed above with respect to their respective base claim.

Furthermore, with respect to the rejection of claims 2 and 19, Applicant respectfully traverses the rejection. Applicant submits that Howard fails to disclose or suggest that the "sensing end of the electrode [is] placed in the blood vessel proximate to the neural tissue," as recited in claim 2 and similarly recited in claim 19. As discussed above with respect to claim 1, Howard neither discloses, nor suggests, placing an electrode in a blood vessel proximate to neural tissue. Therefore, Howard also fails to disclose or suggest placing the "sensing end of the electrode . . . in the blood vessel proximate to the neural tissue," as recited in claim 2 and similarly recited in claim 19.

With respect to the rejection of claims 3-4 and 20-21, Applicant respectfully traverses the rejection. Applicant submits that Howard fails to disclose or suggest that the “sensing end of the electrode is deployed at a point upstream of a junction with another blood vessel,” as recited in claim 3 and similarly recited in claim 20. Likewise, Applicant submits that Howard fails to disclose or suggest that the “sensing end of the electrode is deployed to a point downstream of the junction,” as recited in claim 4 and similarly recited in claim 21.

In contrast, Howard merely discloses drilling a burr hole into a patient’s brain, and then inserting the shaft 137, which holds the microelectrode 135A, into a region of the patient’s brain, such as the globus pallidus. See, Howard, col. 24, lines 46-58. Applicant has reviewed the Howard reference and has found no mention of inserting an electrode in a blood vessel, let alone “in a blood vessel at a point upstream of a junction with another blood vessel,” as recited in claims 3 and 20, or “to a point downstream of the junction,” as recited in claims 4 and 21.

With respect to the rejection of independent claim 10, Applicant has amended claim 10 to recite that the “electrode is less than 5 μm in diameter.” Applicant submits that Howard neither discloses nor suggests an electrode which is less than 5 μm in diameter. In contrast, although Howard discloses a “fine wire having a diameter in the range of 5 to 200 micrometers,” (col. 26, lines 14-16), Howard also states that each bipolar microelectrode 135A is constructed of a pair of electrical contacts 136. See, Howard, col. 26, line 1-18. Therefore, at a minimum, the microelectrode 135A requires 2 wires, thus, having a diameter of at least 10 micrometers. Accordingly, Applicant submits that Howard fails to disclose each and every feature recited in independent claim 10. Thus, Howard fails to anticipate the invention recited in independent claim 10.

suggest each and every feature recited in claims 6-8, 17, and 22-24. Applicant respectfully requests reconsideration and withdrawal of this rejection.

Claims 9 and 25 stand rejected under 35 U.S.C. §103(a) as being unpatentable over the combination of Howard and Lieber in view of U.S. Patent No. 5,391,147 to Imram. Applicant respectfully traverses the rejection.

The Examiner acknowledges that the combination of Howard and Lieber fails to disclose a cup-like end to the nano-electrodes. However, the Examiner relies on Imram as disclosing a catheter comprising an electrode 221 having a cup shaped end. The Examiner contends that it would have been obvious to one of ordinary skill in the art at the time of the invention to combine Howard, Lieber, and Imram to achieve the claimed invention.

Claim 9 depends from claim 1. Claim 25 depends from claim 18. Claims 9 and 25 recite features in addition to those set forth in their respective base claim. Applicant submits that Imram fails to disclose or suggest the features acknowledged by the Examiner to be missing from Howard and Lieber with respect to claims 1 and 18. Accordingly, Applicant submits that the combination of Howard, Lieber, and Imram fails to disclose or suggest each and every feature recited in claims 9 and 25. Applicant respectfully requests reconsideration and withdrawal of this rejection.

Claims 11, 12, 15, 16, 32, and 33 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Howard in view of U.S. Patent No. 5, 883, 603 to Kovacs et al. ("Kovacs") and/or U.S. Patent No. 4,913,160 to John. Applicant respectfully traverses the rejection.

The Examiner acknowledges that Howard fails to disclose the components of a microprocessor. However, the Examiner relies on Kovacs and/or John as disclosing implantable devices containing electrodes that have amplifiers, digital converters, multiplexers, and

Claims 32-36 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Howard in view of U.S. Patent No. 6,374,140 to Rise. Applicant respectfully traverses this rejection.

The Examiner acknowledges that Howard fails to disclose the features of claims 32-36. However, the Examiner relies on Rise as disclosing a device having a sensor 20 with an electrode for measuring electrical activity of the brain, a signal processor 30 including a filter 200 for filtering the signal received from the electrode, wherein the signal processor 30 performs extraction and pattern recognition of the signal to determine a brain state. The Examiner contends that it would have been obvious to one of ordinary skill in the art at the time of the invention to combine Howard and Rise to achieve the claimed invention.

Claims 32-36 depend from claim 1, and recite features in addition to those set forth in base claim 1. Applicant submits that Rise fails to disclose or suggest the features acknowledged by the Examiner to be missing from Howard with respect to claim 1. Accordingly, Applicant submits that the combination of Howard and Rise fails to disclose or suggest each and every feature recited in claims 32-36. Applicant respectfully requests reconsideration and withdrawal of the rejection.

Added Claims

New claim 39 recites features similar to those set forth in claims 1 and 18, as well as additional features. Applicant submits that new claim 39 is patentable over the prior art of record.

New claim 40 depends from claim 10, and recites features in addition to those set forth in claim 10. Applicant submits that added claim 40 is patentable for at least the same reasons as discussed above with respect to claim 10.


CONCLUSION

Each and every point raised in the Office Action dated July 7, 2006 has been addressed on the basis of the above amendments and remarks. In view of the foregoing it is believed that claims 1-36 and 39-40 are in condition for allowance and it is respectfully requested that the application be reconsidered and that all pending claims be allowed and the case passed to issue.

If there are any other issues remaining which the Examiner believes could be resolved through a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

Dated: October 5, 2006

Respectfully submitted,

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